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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,178	06/19/2001	Wendy Naimark	12013/58201	9892
23838	7590	12/21/2007		
KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005				
			EXAMINER MACNEILL, ELIZABETH	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 12/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/883,178	<b>Applicant(s)</b> NAIMARK ET AL.	
	<b>Examiner</b> Elizabeth R. MacNeill	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 13-18 and 24-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-18 and 24-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 13,14,16-18,24,25, and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman et al (US 5,833,652) in view of Theeuwes (US 4,552,555).

Preissman teaches a mixing catheter with a first lumen (10) and a second lumen (12) with a mixing chamber (area with holes 14) and an exit orifice (16). The passageways (14) allow the second lumen and the mixing chamber to communicate, but do not contain a selectively permeable membrane.

Theeuwes teaches a device for modifying fluid moving through a vessel comprising a first lumen (45 to proximal portion of 60) with an exit orifice (at 62b), a second lumen (45 distal of chamber 60), a mixing chamber (60 up to membrane 64), and a passageway (64) between the mixing chamber and the second lumen containing a selectively permeable membrane (Col 6 line 60) which can either extract or add a component to the fluid (Col 6 proximate line 60). The filter (68) prevents bacteria from being delivered to the patient and the release rate controlling film (67) prevents the active agent from being delivered to the patient at a rate unsuitable for the patient.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the selectively permeable membrane of Theeuwes into the passageways (14) of Preissman because the membrane and the dual lumens would perform the same operations in combination and one of ordinary skill in the art would have expected that adding the membrane would produce the predictable result of adding or extracting a component from a medical fluid. Additionally, either membrane (67 or 68) would either prevent bacteria from harming the patient or prevent an overdose or under dose from being administered. See Col 7 lines 1-31.

As to claim 14, see lumen within coil 18; claims 16,25,29, 30, Col 6 proximate line 60 Theeuwes; claim 24, coil 18.

3. Claims 15 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Preissman and Theeuwes as applied to claim 13 above, and further in view of Guirguis (US 4,953,561).

As to claim 26, Preissman and Theeuwes do not teach the use of a glass microfiber membrane. Guirguis teaches a glass microfiber membrane (Col 3 line 50) with a medical fluid handling device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a glass microfiber filter as a function equivalent to the preamble membrane of Theeuwes.

As to claim 15, Preissman and Theeuwes do not teach a source of vacuum in communication with the second lumen. Guirguis teaches a syringe which is used as a source of vacuum which also fluid to pass through the filter (12) and trap particles. It

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would have been obvious to one of ordinary skill in the art at the time the invention was made to use a source of vacuum in the second lumen in order to remove particles from the solution in the first lumen.

### ***Response to Arguments***

4. Applicant's arguments filed 21 November 2007 have been fully considered but they are not persuasive. Applicant has argued that there would be no reason to combine the permeable membrane of Theeuwes with the device of Preissman. First, with regards to the 102 rejections of the previous examiner, the applicant argued that the permeable membrane was not disclosed in Preissman, but did not argue that it would not be obvious to incorporate a permeable membrane. Theeuwes teaches the benefits of a permeable membrane at Col 7 lines 1-31, including preventing bacteria from harming the patient or preventing an overdose or under dose from being administered. The rejection is maintained.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

